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COMPLIANCE POLICY GUIDE

SUBSTITUTING ALBUTEROL HFA INHALERS FOR ALBUTEROL CFC INHALERS

BACKGROUND: The U.S. Food and Drug Administration (FDA) has published final rules to amend its regulation on the use of ozone-depleting substances (ODSs) in medical products. This rule states that as of December 31, 2008, production and sale of single ingredient albuterol chlorofluorocarbon (CFC) metered-dose inhalers (MDI) must cease.

GOAL: To provide a guide to pharmacists regarding substitution when refilling prescriptions written for albuterol MDIs.

POLICY:

1. If a pharmacy has a prescription with valid refills for an albuterol MDI that has been previously filled with a CFC product and the medical practitioner did not specify CFC on the prescription, the pharmacist may substitute a hydrofluoroalkane (HFA) MDI for the remaining refills without seeking permission of the medical practitioner, provided:
2. The pharmacist specifically counsels the patient about the change, including:
 - a. The reason for the change, and
 - b. Any differences the patient may experience.

This substantive policy statement is advisory only. A substantive policy statement does not include internal procedural documents that only affect the internal procedures of the agency and does not impose additional requirements or penalties on regulated parties or include confidential information or rules made in accordance with the Arizona Administrative Procedure Act. If you believe that this substantive policy statement does impose additional requirements or penalties on regulated parties you may petition the agency under A.R.S. § 41-1033 for a review of the statement.